JUN 16 2000

DENTSPLY

510(k) SUMMARY

NAME & ADDRESS:

DENTSPLY International
570 West College Avenue
P.O. Box 872
York, PA 17405-0872
(717) 845-7511
Fax (717) 854-2343

K000946

P. J. Lehn Telefax (717) 849-4343

CONTACT: P. Jeffery Lehn

DATE PREPARED:

TRADE OR PROPRIETARY NAME:
TRUBYTE® DENTURE CLEANSER/POLISHING COMPOUND

CLASSIFICATION NAME: Denture cleanser 872.3520

PREDICATE DEVICE: NUPRO® T Prophylaxis Paste with Fluoride & Triclosan K000169

DEVICE DESCRIPTION: TRUBYTE® DENTURE CLEANSER/POLISHING COMPOUND is a pasty, colloidal suspension of pumice containing triclosan. The device is designed for professional use to clean, smooth and polish the surfaces of dental appliances and prostheses which have been removed from the mouth.

INTENDED USE: TRUBYTE® DENTURE CLEANSER/POLISHING COMPOUND is to be used for professional cleaning and polishing of plastic oral appliances and prostheses, which have been removed from the mouth.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in TRUBYTE® DENTURE CLEANSER/POLISHING COMPOUND have been used in the predicate device or are safe for dental use.

The components not found in the predicate are found in many pharmaceutical preparations or personal care products or cosmetic. They enjoy an excellent safety record when used in appropriate quantities.

TRUBYTE® DENTURE CLEANSER/POLISHING COMPOUND is not indicated for internal use. Safety concerns are, therefore, limited to skin and possible eye exposure. This device presents minimal risk via skin or eye exposure. The device was evaluated and found to be a slight ocular irritant.

We believe that the prior use of the components of TRUBYTE® DENTURE CLEANSER/ POLISHING COMPOUND in legally marketed products, the performance information provided, and the results of biocompatibility testing, support the safety and effectiveness of TRUBYTE® DENTURE CLEANSER/POLISHING COMPOUND for the indicated uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2000

Mr. P. Jeffrey Lehn
Director, Corporate Compliance
and Regulatory Affairs
DENTSPLY International
570 West College Avenue
P.O. Box 872
York, Pennsylvania 17405-0872

Re: K000996
Trade Name: Trubyte® Denture Cleanser/Polishing Compound
Regulatory Class: I
Product Code: EFT
Dated: March 27, 2000
Received: March 28, 2000

Dear Mr. Lehn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Kathleen Quinlan for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e))

510(k) NUMBER (IF KNOWN): K000996

DEVICE NAME: TRUBYTE® DENTURE CLEANSER/POLISHING COMPOUND

INDICATIONS FOR USE:

TRUBYTE® DENTURE CLEANSER/POLISHING COMPOUND is to be used for professional cleaning and polishing of plastic oral appliances and prostheses, which have been removed from the mouth.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.)

Susan Runner Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000996

Prescription Use ___ OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)